

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Display Date	9-21-01
Publication Date	9-24-01
Certifier	STEESE

[Docket No. 00N-1543]

**Draft Guidance for Industry; Electronic Records; Electronic Signatures, Glossary of Terms; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms." The draft guidance defines terms that will be used in FDA's guidances that describe the agency's current thinking on principles and procedures for creating, modifying, maintaining, archiving, retrieving, and transmitting electronic records and electronic signatures in order to ensure that electronic records and electronic signatures are trustworthy, reliable, and compatible with FDA's public health responsibilities.

**DATES:** Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance entitled "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms" to the Division of Compliance Information and Quality Assurance (HFC-240), Office of Enforcement, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

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Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Paul J. Motise, Office of Enforcement (HFC-240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0383, e-mail: [pmotise@ora.fda.gov](mailto:pmotise@ora.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance entitled "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms." In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published a regulation providing criteria under which the agency considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper ("part 11" (21 CFR part 11)). The preamble to part 11 stated that the agency anticipated issuing supplemental guidance documents and would afford all interested parties the opportunity to comment on draft guidance documents. Therefore, FDA is making this draft guidance available for public comment.

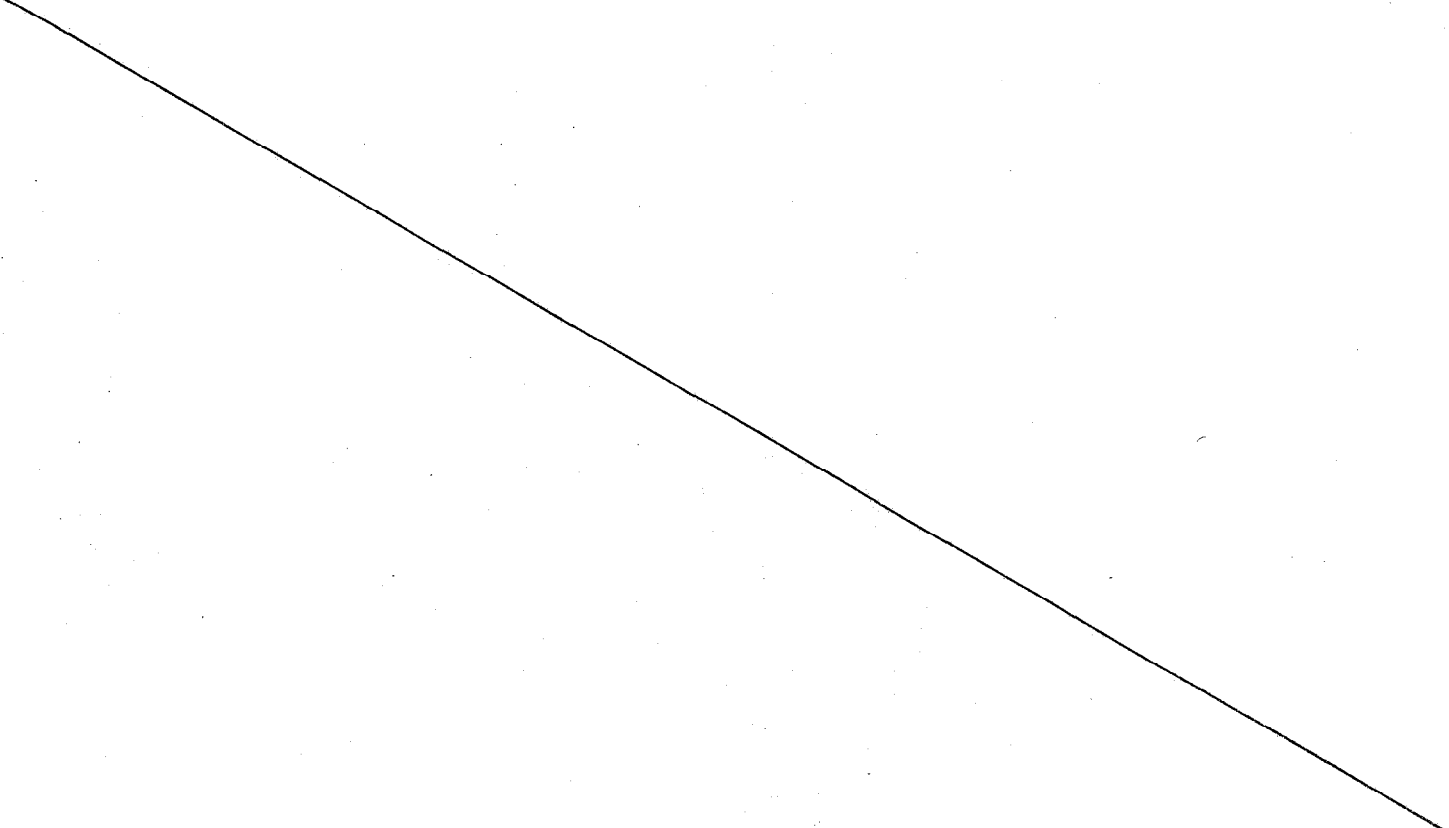
The draft guidance defines terms that will be used in other FDA guidance documents about part 11. FDA believes that rather than repeat definitions in multiple guidances it would be more efficient to consolidate them in one common document. The glossary of terms is intended to assist people who must meet part 11 requirements; it may also assist FDA staff who apply part 11 to persons subject to the regulation.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a companion draft document entitled "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation" and is offering the opportunity to comment on it, as well. By direct reference, the companion draft document incorporates definitions contained in the draft glossary of terms.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on terms and their definitions as used in guidance documents about electronic records and electronic signatures in the context of part 11. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## **II. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

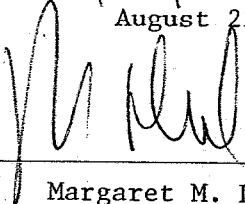


### III. Electronic Access

Persons with access to the Internet may obtain the document at [http://www.fda.gov/ora/compliance\\_ref/Part11](http://www.fda.gov/ora/compliance_ref/Part11).

Dated: 8/23/01

August 23, 2001.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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